K010845 p1/2

APR 1 8 2001

Special 510(k): Device Modification for the Osteonics® Spinal System Summary of Safety and Effectiveness

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Karen Ariemma Regulatory Affairs Specialist
Date of Summary Preparation:	March 19, 2001

Device Identification

Proprietary Name:	Osteonics® Spinal System
Common Name:	Spinal Fixation Appliances
Classification Name and Reference:	Spinal Interlaminal Fixation Orthosis 21 CFR 888.3050 Pedicle Screw Spinal System 21 CFR 888.3070

Predicate Device Identification

The features of the subject Diapason Screws are substantially equivalent to features of the Osteonics® Spinal System Conical Screws which were determined substantially equivalent via 510(k)s K951725 and K983152.

Description of Device Modification

The design change involves color coding the screws via anodization and increasing the threaded length of the screw. All other features of the screw remain the same.

Intended Use

The subject Diapason screws, like the predicate OSS Conical Screws, are intended for use only with the other components of the commercially available Osteonics® Spinal System. The uses for the legally marketed Osteonics® Spinal System are as follows:

As a posterior, non-pedicle screw system of the T4-S2 spine, the Osteonics® Spinal System is indicated for:

- Long and short curve scoliosis
- Vertebral fracture or dislocation
- Spondylolisthesis

- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
- Previously failed fusion
- Spinal tumor

Pedicular Use:

- When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the Osteonics® Spinal System is indicated for one or more of the following: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

- In addition, the Osteonics® Spinal system is indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint, having fusions with autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (with pedicle placement at L3 and below) with removal of the implants after the development of a solid fusion mass.

Statement of Technological Comparison:

Fatigue testing demonstrates the comparable mechanical properties of the subject Diapason Screw to the predicate OSS Screw.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2001

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401

Re: K010845
Trade/Device Name: Osteonics™ Spinal System
Regulation Number: 888.3070
Regulatory Class: Class II
Product Code: MNH, MNI, KWP
Dated: March 19, 2001
Received: March 21, 2001

Dear Ms. Ariemma:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010845

Device Name: Diapason Screws

Indications For Use

The subject components, Diapason Screws, are single-use devices which are sold non-sterile and are intended for use only with the other components of the commercially available Osteonics® Spinal System.

The uses for the legally marketed Osteonics® Spinal System are as follows:

As a posterior, non-pedicle screw system of the T4-S2 spine, the Osteonics® Spinal System is indicated for:

- Long and short curve scoliosis
- Vertebral fracture or dislocation
- Spondylolisthesis
- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
- Previously failed fusion
- Spinal tumor

Pedicular Use:

- When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the Osteonics® Spinal System is indicated for one or more of the following: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

- In addition, the Osteonics® Spinal system is indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint, having fusions with autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (with pedicle placement at L3 and below)with removal of the implants after the development of a solid fusion mass.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Prescription Use X OR Over-The-Counter Use ____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

510(k) Number K010845